Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
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Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
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Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish requirements for product tracing, verification, and product identification for certain drug products that are distributed in the United States. Many of the terms used in these requirements are defined in section 581 of the FD&C Act (21 U.S.C. 360eee).

FDA is issuing this guidance to interpret the terms used in the definition of *suspect product* set forth in section 581(21) of the FD&C Act, and the definition of *illegitimate product* set forth in section 581(8) of the FD&C Act, in order to assist trading partners in meeting verification obligations (including notification) under sections 582(b)(4), (c)(4), (d)(4), and (e)(4), respectively.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Definitions of *Suspect Product* and *Illegitimate Product*

On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which added section 581 to the FD&C Act, sets forth the definitions of "suspect product" and

[1] This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the FDA.

"illegitimate product", among other terms. *Suspect product* is defined in section 581(21) of the FD&C Act, and *illegitimate product* is defined in section 581(8) of the FD&C Act:

> SUSPECT PRODUCT—The term 'suspect product' means a product for which there is reason to believe that such product—
>
> (A) is potentially counterfeit, diverted, or stolen;
>
> (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
>
> (C) is potentially the subject of a fraudulent transaction; or
>
> (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
>
> ILLEGITIMATE PRODUCT—The term 'illegitimate product' means a product for which credible evidence shows that the product—
>
> (A) is counterfeit, diverted, or stolen;
>
> (B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
>
> (C) is the subject of a fraudulent transaction; or
>
> (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

B. Scope of This Guidance

This guidance applies to the definitions of *suspect product* and *illegitimate product* as described in sections 581(21) and 581(8) of the FD&C Act, specifically as those terms are used to describe trading partners' verification obligations (including notification) under sections 582(b)(4), (c)(4), (d)(4), and (e)(4), respectively.

This guidance is intended to help industry identify suspect and illegitimate product in the prescription drug distribution system in the United States by interpreting certain terms used in the definitions of *suspect product* and *illegitimate product*. Trading partners are required to take specific actions if they identify such products.[2]

The Agency intends to issue additional guidance that will address other aspects of the verification requirements in section 582. In addition, the Agency previously issued, pursuant to section 582(h)(2)(A)(iii) of the FD&C Act, the *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* guidance for industry that describes the

[2] See, e.g., sections 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.

processes for notifying FDA and trading partners of illegitimate product, as well as terminating those notifications.[3,4]

III. INTERPRETATION OF TERMS

In order to comply with the verification provisions (including notification) of section 582 of the FD&C Act, trading partners[5] (manufacturers, repackagers, wholesale distributors, and dispensers) must be able to identify a suspect product and make a determination about whether that product is an illegitimate product.

To help satisfy these obligations, trading partners should focus on the potential supply chain security threats listed in the *suspect product* and *illegitimate product* definitions. These threats include drugs that are, or may be, counterfeit, diverted, stolen, intentionally adulterated, unfit for distribution, or the subject of a fraudulent transaction.

FDA is clarifying its interpretiation of the terms *counterfeit*, *diverted*, *fraudulent transaction*, and *unfit for distribution* to aid trading partners in determining whether a product is suspect and/or illegitimate.

While this guidance does not create an exhaustive list of the circumstances that may result in a counterfeit drug, a diverted drug, a fraudulent transaction, or a drug that is unfit for distribution, it describes the most common scenarios that FDA believes trading partners will encounter.

A. Counterfeit

FDA interprets the term counterfit drug as used in sections 581(8) and (21), and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), to mean:

> [A] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.[6]

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[3] See the FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*, available on the FDA Drugs guidance web page under Clinical/Medical. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

[4] This guidance document, once the relevant portion is finalized, is intended to also help manufacturers identify when there is a specific high risk that could increase the likelihood of an illegitimate product entering the pharmaceutical distribution supply chain.

[5] *Trading partner* is defined in section 581(23)(A) of the FD&C Act (21 U.S.C. 360eee(23)(A)). Although third-party logistics providers are also considered trading partners under section 581(23)(B), the requirements of section 582(a)-(e) are not applicable to them.

[6] Section 201(g)(2) of the FD&C Act.

B. Diverted

For purposes of section 581(8) and (21) of the FD&C Act, and the verification obligations (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), FDA interprets the term *diverted* to refer to a:

1. Product that left the prescription drug distribution system in the United States and is reintroduced in a transaction with an authorized trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced into the U.S. prescription drug distribution system to an authorized trading partner; or

2. Product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. prescription drug distribution systemto an authorized trading partner.

A product generally would not be considered diverted as described in B.1, above, and therefore would not be a suspect or illegitimate product under DSCSA, if a trading partner obtains that drug product:

- Through surveillance activities outside the U.S. prescription drug distribution system; or

- From a consumer or patient who obtained the product from outside the the U.S. prescription drug distribution system, unless the trading partner has reason to belive that the product could be introduced into the U.S. prescription drug distribution system to an authorized trading partner.

C. Fraudulent Transaction

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), FDA interprets the term *fraudulent transaction* as referring to a transaction in which the transaction information, transaction history, or transaction statement contains falsified information.

D. Unfit for Distribution

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), FDA interprets the term *unfit for distribution* as referring to a prescription drug whose sale would violate the FD&C Act. This includes prescription drugs identified as suspect or illegitimate (see 582(c)(4) of the FD&C Act); adulterated (see section 501), including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (see section 501(2)(B) of the FD&C Act); or misbranded (see section 502 of the FD&C Act).